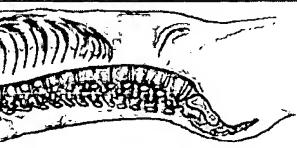


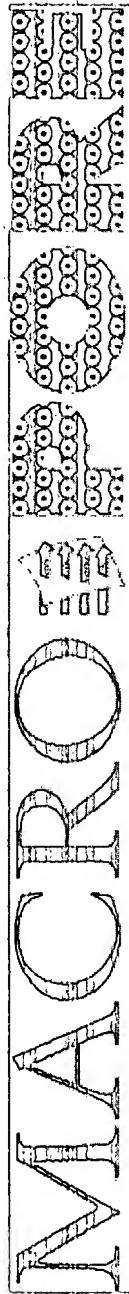
MacroPore^{SS}: Biobioresorbable Antithrombotic Film



©GBGaya Cornwall PhD Bill DuBois, Ken Kleinhennz

MacroPore, Inc.

March 2001



Advanced Resorbable Solutions

Macropoles:

Anti-Adhesion Film

o RATIONALE:

Scarring adjacent to the exiting nerve roots has been implicated in failed back syndrome.

STRATEGY:

510(k) Submission: January 19, 2001*

⁵ (this will not have the same indications as Gliatech - PMA)

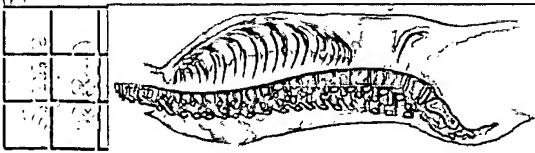
MARKET SIZES

394
395
396
\$254

1. *On the Nature of the Human Species* (1859) by Charles Darwin, which introduced the theory of evolution by natural selection.

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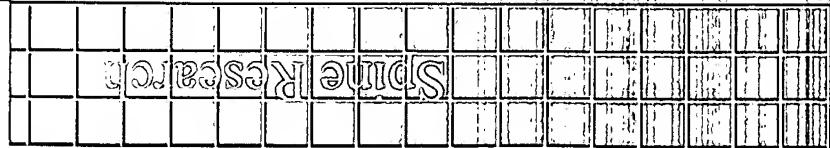
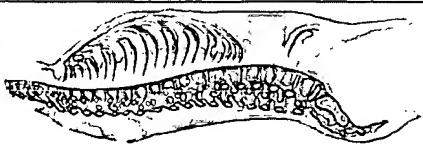


Simple Recursive

MacroPore TS[®]

Indications for Use (submitted)

- 1) Surgical repair of fractured orbital floors
- 2) Surgical repair of nasal septum and perforated ear drum membrane
- 3) Used as a protective sheathing to facilitate osteogenesis
- 4) For surgical repair of urethral anatomy and repair of urethral strictures
- 5) To prevent synostosis in completed corrective surgery for cranial fusions and forearm fractures
- 6) Lesser soft-tissue fibrosis or bony growth
- 7) As a temporary covering for perirectal surgical oropharyngeal fistulae during Not suitable for permanent management due to resorption

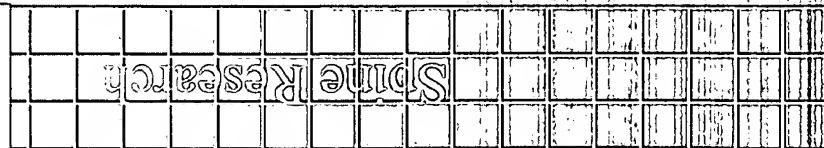
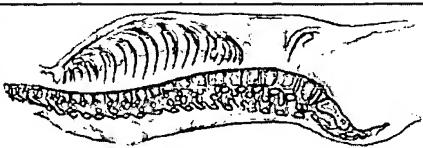


MacroPore TS[®]

Indications for Use (submitted)

- 8) Guided tissue regeneration between the teeth and gingival margin
- 9) Tympanic membrane repairs
- 10) Dural coverings and neural repair
- 11) Tendon anastomosis
- 12) Temporary joint spacer
- 13) Wound dressings
- 14) Scar coverings
- 15) Covering for gastroschisis

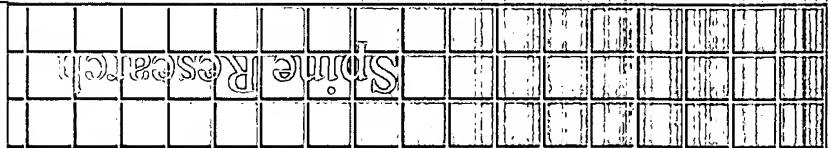
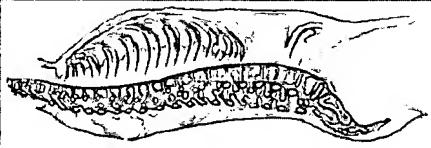
Note: Intended to be used when permanent implants are required.



MacroPore TS:

Anti-Adhesion Study

L5-L6 Laminectomy-Dura

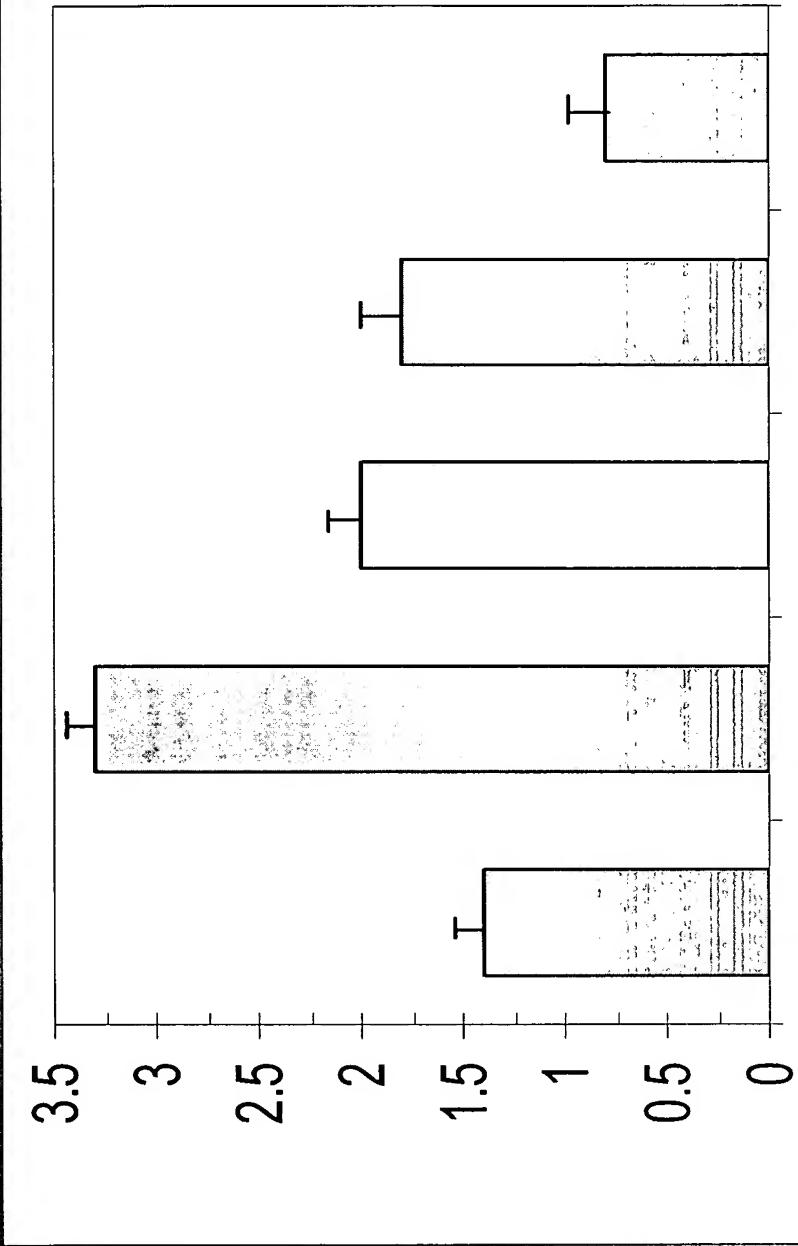


Spine Response

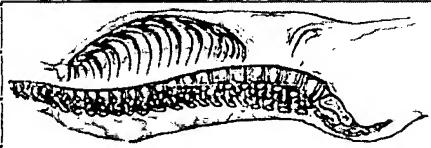
MacroPore TS:

Anti-Adhesion Study

Total Collagen Content of Epidural Space

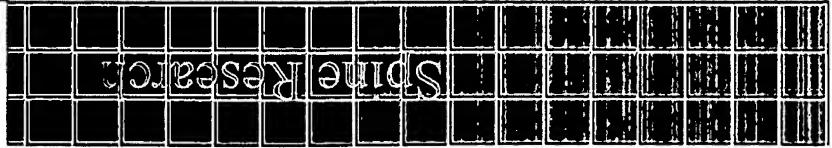
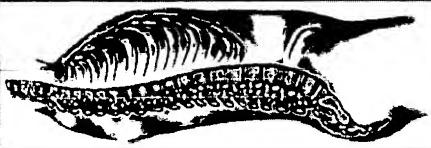
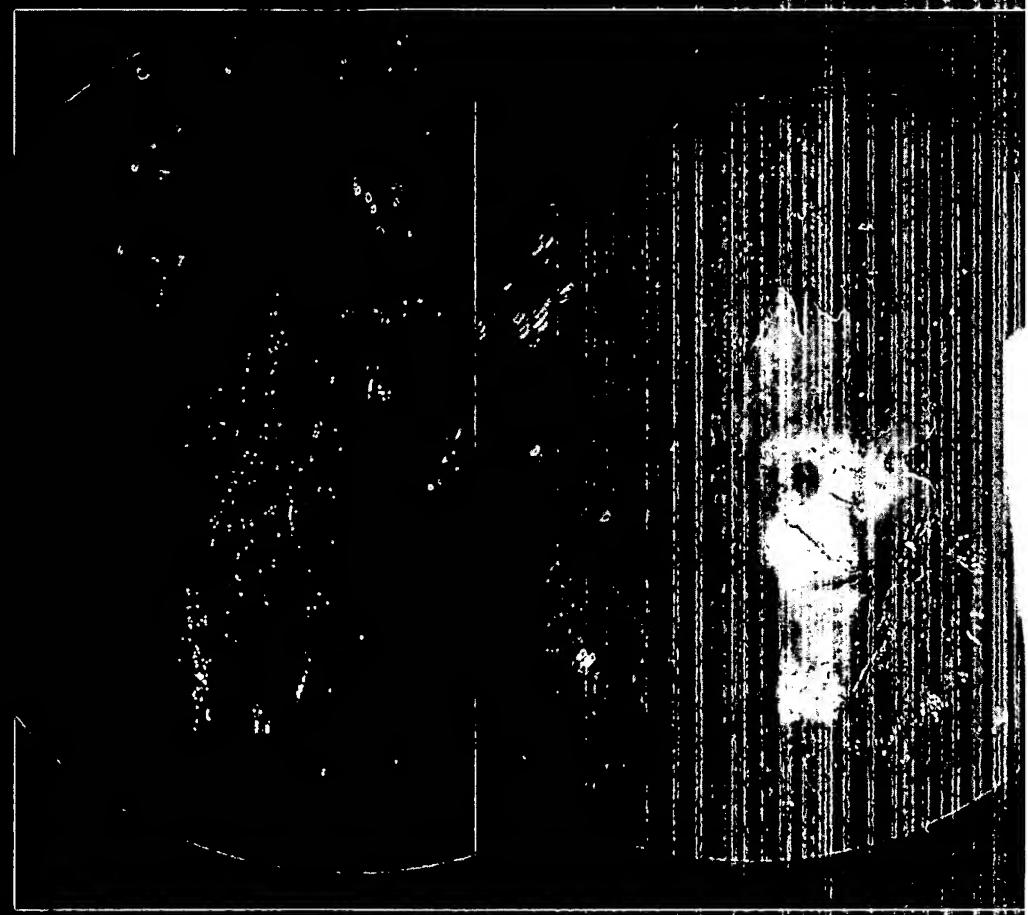


Normal Untreated Hyaluronan Adcon-L Macropore



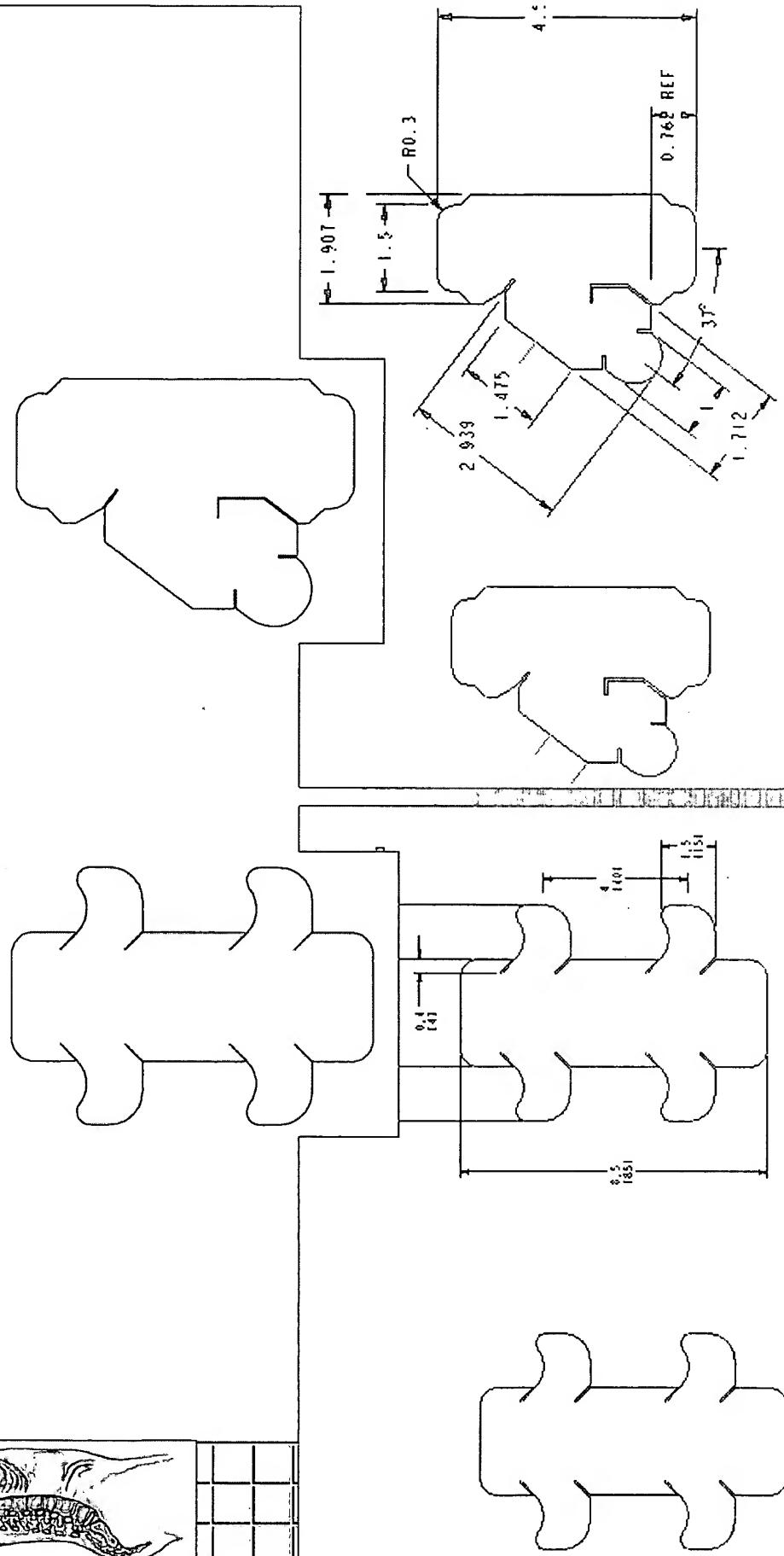
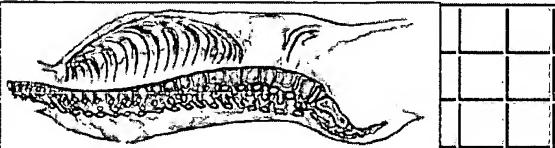
Macropore TS:

Anti-Adhesion Film



MacroPore TTS[®]

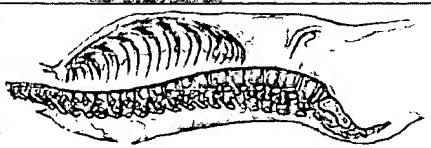
Anti-Adhesion Film



TYPE : PART NAME : 803-0003-REV-1 SIZE : A

TYPE : PART NAME : 803-0001-REV-01 SIZE : A

Literature Review



- The degradation of PLA implants does not seem to create any sinus formations or significant pH variance according to clinical data and animal testing
- Properly sterilized PLA does not appear to cause unusual infection or foreign body reaction

- PLA is more accepted by the body than PGA, another common biodegradable material

Conclusions

- o Early pre-clinical results (rat model) demonstrate quantitative reduction in collagen content – associated with scar.
- o PLA is a biocompatible & safe material.
- o Surgeon Interest & Excitement in this product is STRONG!

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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185 | 186 | 187 | 188 | 189 | 190 | 191 | 192 | 193 | 194 | 195 | 196 | 197 | 198 | 199 | 200 | 201 | 202 | 203 | 204 | 205 | 206 | 207 | 208 | 209 | 210 | 211 | 212 | 213 | 214 | 215 | 216 | 217 | 218 | 219 | 220 | 221 | 222 | 223 | 224 | 225 | 226 | 227 | 228 | 229 | 230 | 231 | 232 | 233 | 234 | 235 | 236 | 237 | 238 | 239 | 240 | 241 | 242 | 243 | 244 | 245 | 246 | 247 | 248 | 249 | 250 | 251 | 252 | 253 | 254 | 255 | 256 | 257 | 258 | 259 | 260 | 261 | 262 | 263 | 264 | 265 | 266 | 267 | 268 | 269 | 270 | 271 | 272 | 273 | 274 | 275 | 276 | 277 | 278 | 279 | 280 | 281 | 282 | 283 | 284 | 285 | 286 | 287 | 288 | 289 | 290 | 291 | 292 | 293 | 294 | 295 | 296 | 297 | 298 | 299 | 300 | 301 | 302 | 303 | 304 | 305 | 306 | 307 | 308 | 309 | 310 | 311 | 312 | 313 | 314 | 315 | 316 | 317 | 318 | 319 | 320 | 321 | 322 | 323 | 324 | 325 | 326 | 327 | 328 | 329 | 330 | 331 | 332 | 333 | 334 | 335 | 336 | 337 | 338 | 339 | 340 | 341 | 342 | 343 | 344 | 345 | 346 | 347 | 348 | 349 | 350 | 351 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518 | 519 | 520 | 521 | 522 | 523 | 524 | 525 | 526 | 527 | 528 | 529 | 530 | 531 | 532 | 533 | 534 | 535 | 536 | 537 | 538 | 539 | 540 | 541 | 542 | 543 | 544 | 545 | 546 | 547 | 548 | 549 | 550 | 551 | 552 | 553 | 554 | 555 | 556 | 557 | 558 | 559 | 560 | 561 | 562 | 563 | 564 | 565 | 566 | 567 | 568 | 569 | 570 | 571 | 572 | 573 | 574 | 575 | 576 | 577 | 578 | 579 | 580 | 581 | 582 | 583 | 584 | 585 | 586 | 587 | 588 | 589 | 590 | 591 | 592 | 593 | 594 | 595 | 596 | 597 | 598 | 599 | 600 | 601 | 602 | 603 | 604 | 605 | 606 | 607 | 608 | 609 | 610 | 611 | 612 | 613 | 614 | 615 | 616 | 617 | 618 | 619 | 620 | 621 | 622 | 623 | 624 | 625 | 626 | 627 | 628 | 629 | 630 | 631 | 632 | 633 | 634 | 635 | 636 | 637 | 638 | 639 | 640 | 641 | 642 | 643 | 644 | 645 | 646 | 647 | 648 | 649 | 650 | 651 | 652 | 653 | 654 | 655 | 656 | 657 | 658 | 659 | 660 | 661 | 662 | 663 | 664 | 665 | 666 | 667 | 668 | 669 | 670 | 671 | 672 | 673 | 674 | 675 | 676 | 677 | 678 | 679 | 680 | 681 | 682 | 683 | 684 | 685 | 686 | 687 | 688 | 689 | 690 | 691 | 692 | 693 | 694 | 695 | 696 | 697 | 698 | 699 | 700 | 701 | 702 | 703 | 704 | 705 | 706 | 707 | 708 | 709 | 710 | 711 | 712 | 713 | 714 | 715 | 716 | 717 | 718 | 719 | 720 | 721 | 722 | 723 | 724 | 725 | 726 | 727 | 728 | 729 | 730 | 731 | 732 | 733 | 734 | 735 | 736 | 737 | 738 | 739 | 740 | 741 | 742 | 743 | 744 | 745 | 746 | 747 | 748 | 749 | 750 | 751 | 752 | 753 | 754 | 755 | 756 | 757 | 758 | 759 | 760 | 761 | 762 | 763 | 764 | 765 | 766 | 767 | 768 | 769 | 770 | 771 | 772 | 773 | 774 | 775 | 776 | 777 | 778 | 779 | 770 | 771 | 772 | 773 | 774 | 775 | 776 | 777 | 778 | 779 | 780 | 781 | 782 | 783 | 784 | 785 | 786 | 787 | 788 | 789 | 790 | 791 | 792 | 793 | 794 | 795 | 796 | 797 | 798 | 799 | 800 | 801 | 802 | 803 | 804 | 805 | 806 | 807 | 808 | 809 | 8010 | 8011 | 8012 | 8013 | 8014 | 8015 | 8016 | 8017 | 8018 | 8019 | 8020 | 8021 | 8022 | 8023 | 8024 | 8025 | 8026 | 8027 | 8028 | 8029 | 8030 | 8031 | 8032 | 8033 | 8034 | 8035 | 8036 | 8037 | 8038 | 8039 | 8040 | 8041 | 8042 | 8043 | 8044 | 8045 | 8046 | 8047 | 8048 | 8049 | 8050 | 8051 | 8052 | 8053 | 8054 | 8055 | 8056 | 8057 | 8058 | 8059 | 8060 | 8061 | 8062 | 8063 | 8064 | 8065 | 8066 | 8067 | 8068 | 8069 | 8070 | 8071 | 8072 | 8073 | 8074 | 8075 | 8076 | 8077 | 8078 | 8079 | 8080 | 8081 | 8082 | 8083 | 8084 | 8085 | 8086 | 8087 | 8088 | 8089 | 8090 | 8091 | 8092 | 8093 | 8094 | 8095 | 8096 | 8097 | 8098 | 8099 | 80100 | 80101 | 80102 | 80103 | 80104 | 80105 | 80106 | 80107 | 80108 | 80109 | 80110 | 80111 | 80112 | 80113 | 80114 | 80115 | 80116 | 80117 | 80118 | 80119 | 80120 | 80121 | 80122 | 80123 | 80124 | 80125 | 80126 | 80127 | 80128 | 80129 | 80130 | 80131 | 80132 | 80133 | 80134 | 80135 | 80136 | 80137 | 80138 | 80139 | 80140 | 80141 | 80142 | 80143 | 80144 | 80145 | 80146 | 80147 | 80148 | 80149 | 80150 | 80151 | 80152 | 80153 | 80154 | 80155 | 80156 | 80157 | 80158 | 80159 | 80160 | 80161 | 80162 | 80163 | 80164 | 80165 | 80166 | 80167 | 80168 | 80169 | 80170 | 80171 | 80172 | 80173 | 80174 | 80175 | 80176 | 80177 | 80178 | 80179 | 80180 | 80181 | 80182 | 80183 | 80184 | 80185 | 80186 | 80187 | 80188 | 80189 | 80190 | 80191 | 80192 | 80193 | 80194 | 80195 | 80196 | 80197 | 80198 | 80199 | 80200 | 80201 | 80202 | 80203 | 80204 | 80205 | 80206 | 80207 | 80208 | 80209 | 80210 | 80211 | 80212 | 80213 | 80214 | 80215 | 80216 | 80217 | 80218 | 80219 | 80220 | 80221 | 80222 | 80223 | 80224 | 80225 | 80226 | 80227 | 80228 | 80229 | 80230 | 80231 | 80232 | 80233 | 80234 | 80235 | 80236 | 80237 | 80238 | 80239 | 80240 | 80241 | 80242 | 80243 | 80244 | 80245 | 80246 | 80247 | 80248 | 80249 | 80250 | 80251 | 80252 | 80253 | 80254 | 80255 | 80256 | 80257 | 80258 | 80259 | 80260 | 80261 | 80262 | 80263 | 80264 | 80265 | 80266 | 80267 | 80268 | 80269 | 80270 | 80271 | 80272 | 80273 | 80274 | 80275 | 80276 | 80277 | 80278 | 80279 | 80280 | 80281 | 80282 | 80283 | 80284 | 80285 | 80286 | 80287 | 80288 | 80289 | 80290 | 80291 | 80292 | 80293 | 80294 | 80295 | 80296 | 80297 | 80298 | 80299 | 80300 | 80301 | 80302 | 80303 | 80304 | 80305 | 80306 | 80307 | 80308 | 80309 | 80310 | 80311 | 80312 | 80313 | 80314 | 80315 | 80316 | 80317 | 80318 | 80319 | 80320 | 80321 | 80322 | 80323 | 80324 | 80325 | 80326 | 80327 | 80328 | 80329 | 80330 | 80331 | 80332 | 80333 | 80334 | 80335 | 80336 | 80337 | 80338 | 80339 | 80340 | 80341 | 80342 | 80343 | 80344 | 80345 | 80346 | 80347 | 80348 | 80349 | 80350 | 80351 | 80352 | 80353 | 80354 | 80355 | 80356 | 80357 | 80358 | 80359 | 80360 | 80361 | 80362 | 80363 | 80364 | 80365 | 80366 | 80367 | 80368 | 80369 | 80370 | 80371 | 80372 | 80373 | 80374 | 80375 | 80376 | 80377 | 80378 | 80379 | 80380 | 80381 | 80382 | 80383 | 80384 | 80385 | 80386 | 80387 | 80388 | 80389 | 80390 | 80391 | 80392 | 80393 | 80394 | 80395 | 80396 | 80397 | 80398 | 80399 | 80400 | 80401 | 80402 | 80403 | 80404 | 80405 | 80406 | 80407 | 80408 | 80409 | 80410 | 80411 | 80412 | 80413 | 80414 | 80415 | 80416 | 80417 | 80418 | 80419 | 80420 | 80421 | 80422 | 80423 | 80424 | 80425 | 80426 | 80427 | 80428 | 80429 | 80430 | 80431 | 80432 | 80433 | 80434 | 80435 | 80436 | 80437 | 80438 | 80439 | 80440 | 80441 | 80442 | 80443 | 80444 | 80445 | 80446 | 80447 | 80448 | 80449 | 80450 | 80451 | 80452 | 80453 | 80454 | 80455 | 80456 | 80457 | 80458 | 80459 | 80460 | 80461 | 80462 | 80463 | 80464 | 80465 | 80466 | 80467 | 80468 | 80469 | 80470 | 80471 | 80472 | 80473 | 80474 | 80475 | 80476 | 80477 | 80478 | 80479 | 80480 | 80481 | 80482 | 80483 | 80484 | 80485 | 80486 | 80487 | 80488 | 80489 | 80490 | 80491 | 80492 | 80493 | 80494 | 80495 | 80496 |